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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,670	09/08/1998	NOBUAKI NAKAGAWA	FJN-063	8271

28381 7590 04/17/2007

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
ROMEO, DAVID S	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/051,670	NAKAGAWA ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 6* is/are allowed.

6)☒ Claim(s) *5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0501*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Ex parte prosecution is resumed. Claims 1, 2, 5, 6 are pending and being examined.

New Formal Matters, Objections, and/or Rejections:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Patent No. 7,094,564 ('564 patent) in view of U. S. Patent No. 7,078,493 ('493 patent).

This rejection is based on an effective filing date of 03/15/1995 for the '564 patent.

A 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"

(B) Explain the meaning of a term used in the primary reference; or

(C) Show that a characteristic not disclosed in the reference is inherent.

The '564 patent discloses a polypeptide having the amino acid sequence SEQ ID NO: 2 or having the amino acid sequence encoded by the cDNA in ATCC Deposit No. 75899 (column 3, last full paragraph; column 6, full paragraph 3). The polypeptide is preferably provided in an isolated form (column 7, full paragraph 1).

The amino acid sequence of the '564 patent's SEQ ID NO: 2 or the amino acid sequence encoded by the cDNA in ATCC Deposit No. 75899 is identical to the amino acid sequence of the present application's SEQ ID NO: 3, as indicated below (Qy = SEQ ID NO: 3):

```
  Query Match             100.0%;  Score 2200;  DB 1;  Length 401;
  Best Local Similarity   100.0%;  Pred. No. 7.2e-184;
  Matches  401;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60

Qy      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120

Qy     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180

Qy     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240

Qy     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300

Qy     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360
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Qy     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
           |||||||||||||||||||||||||||||||||||||||||||
Db     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
```

The cDNA in ATCC Deposit No. 75899 contains an open reading frame encoding a polypeptide of 401 amino acid residues (SEQ ID NO: 2), as evidenced by the '493 patent (column 3, full paragraph 2). The '493 patent's SEQ ID NO: 2 is also identical to SEQ ID NO: 3 of the present application, as indicated below:

```
  Query Match             100.0%;  Score 2200;  DB 20;  Length 401;
  Best Local Similarity   100.0%;  Pred. No. 7.2e-184;
  Matches  401;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60
           |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60

Qy      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120

Qy     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180

Qy     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240

Qy     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300

Qy     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360

Qy     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
           |||||||||||||||||||||||||||||||||||||||||||
Db     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
```

Accordingly, the '564 patent discloses an isolated protein having an amino acid sequence comprising the present application's SEQ ID NO: 3.

Furthermore, a chemical composition and its properties are inseparable. Therefore, the properties applicant discloses and/or claims, i.e. "having a molecular weight of about 60 KD, wherein said molecular weight is determined by SDS-PAGE under reducing conditions, and

wherein said protein inhibits differentiation or maturation of osteoclasts", are necessarily present in the '564 patent's protein.

Claim 5 is rejected under 35 U.S.C. 102(a) as being anticipated by WO 96/28546 in view of U. S. Patent No. 7,078,493 ('493 patent).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

A 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure; "

(B) Explain the meaning of a term used in the primary reference; or

(C) Show that a characteristic not disclosed in the reference is inherent.

WO 96/28546 discloses a polypeptide having the amino acid sequence SEQ ID NO: 2 or having the amino acid sequence encoded by the cDNA in the deposited clone (page 10, full paragraph 1). The polypeptide is preferably provided in an isolated form (page 11, full paragraph 1). The cDNA is contained in ATCC Deposit No. 75899 (page 6, full paragraph 2).

The amino acid sequence of WO 96/28546's SEQ ID NO: 2 or the amino acid sequence encoded by the cDNA in ATCC Deposit No. 75899 is identical to the amino acid sequence of the present application's SEQ ID NO: 3, as indicated below (Qy = SEQ ID NO: 3):

```
  Query Match             100.0%;  Score 2200;  DB 1;  Length 401;
  Best Local Similarity   100.0%;  Pred. No. 7.2e-184;
  Matches  401;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60
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```
Qy      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120

Qy     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180

Qy     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240

Qy     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300

Qy     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360

Qy     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
           |||||||||||||||||||||||||||||||||||||||||||
Db     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
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The cDNA in ATCC Deposit No. 75899 contains an open reading frame encoding a polypeptide of 401 amino acid residues (SEQ ID NO: 2), as evidenced by the '493 patent (column 3, full paragraph 2). The '493 patent's SEQ ID NO: 2 is also identical to SEQ ID NO: 3 of the present application, as indicated below:

```
  Query Match             100.0%;  Score 2200;  DB 20;  Length 401;
  Best Local Similarity   100.0%;  Pred. No. 7.2e-184;
  Matches  401;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 MNKLLCCALVFLDISIKWTTQETFPPKYLHYDEETSHQLLCDKCPPGTYLKQHCTAKWKT 60

Qy      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 VCAPCPDHYYTDSWHTSDECLYCSPVCKELQYVKQECNRTHNRVCECKEGRYLEIEFCLK 120

Qy     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 HRSCPPGFGVVQAGTPERNTVCKRCPDGFFSNETSSKAPCRKHTNCSVFGLLLTQKGNAT 180

Qy     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 HDNICSGNSESTQKCGIDVTLCEEAFFRFAVPTKFTPNWLSVLVDNLPGTKVNAESVERI 240

Qy     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 KRQHSSQEQTFQLLKLWKHQNKDQDIVKKIIQDIDLCENSVQRHIGHANLTFEQLRSLME 300
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```
Qy     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 SLPGKKVGAEDIEKTIKACKPSDQILKLLSLWRIKNGDQDTLKGLMHALKHSKTYHFPKT 360

Qy     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
           |||||||||||||||||||||||||||||||||||||||||||
Db     361 VTQSLKKTIRFLHSFTMYKLYQKLFLEMIGNQVQSVKISCL 401
```

Accordingly, WO 96/28546 discloses an isolated protein having an amino acid sequence comprising the present application's SEQ ID NO: 3.

Furthermore, a chemical composition and its properties are inseparable. Therefore, the properties applicant discloses and/or claims, i.e. "having a molecular weight of about 60 KD, wherein said molecular weight is determined by SDS-PAGE under reducing conditions, and wherein said protein inhibits differentiation or maturation of osteoclasts", are necessarily present in the WO 96/28546's protein.

Conclusion

Claims 1, 2 and 6 are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
APRIL 10, 2007